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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,463	04/15/2005	Naoyuki Moriya	270434US0PCT	7004

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EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
03/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/531,463	MORIYA ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-22* is/are pending in the application.

4a) Of the above claim(s) *20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/22/207*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment and declaration of Koji Kubota submitted December 12, 2007, wherein claims 1-3 and 6-8 are cancelled and new claims 9-22 are added.

Newly submitted claims 20-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally presented composition claims and the newly submitted method claims are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in different processes, such as a treatment for constipation, activation of the immune system, or as a skin moisturizer.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 9-22 are pending in this application. Claims 20-22 are withdrawn from consideration as being drawn to a non-elected invention. Claims 9-19 are examined on the merits herein.

The following rejections of record made in the previous office action, although applied to newly submitted claims, are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagon et al. (JP 2003-040785, February 13, 2003, machine translation) in view of Japan Food Additive Association (http://www.aureo.co.jp/english/glucan/glucan6.html, table from Explanatory Notes for Products in Existing Food Additives List, published 1999).

Wagon et al. teach an infection-suppressing composition containing β-glucan and heat-treated lactic acid producing bacteria, preferably *Enterococcus faecalis,* for use in food and drink [see abstract]. The amount of the β-glucan-containing material is 0.5-99.5% by weight and the lactic acid producing bacteria 99.5-0.5 percent by weight [see abstract]; or more preferably, 10-90% and 90-10% by weight [0032]. The β-glucan is preferably derived from basidomycete, yeast, bacteria, algae and lichen [see abstract and claim 3].

The limitations "constipation-relieving drug", "immunopotentiator," and "skin moisturizer," as in claims 15-17, are considered intended use or inherent properties of the composition which are not given patentable weight; the claims are considered drawn to the composition only.

Wagon et al. do not exemplify a composition comprising β-1,3-1,6-glucan.

Japan Food Additive Association teaches that β-1,3-1,6-glucan is obtained from Aureobasidium pullulans, is known to activate the immune system, is a health food, and can be used in drinks, sauces, bread, and other foods [table].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising β-1,3-1,6-glucan and dead lactic acid bacterium *Enterococcus faecalis* cells and to incorporate that composition into food or drink. Wagon et al. teach an infection-suppressing food or drink composition comprising β-glucan and the aforementioned dead bacterium cells and also teach that the β-glucan can be obtained from yeast. The skilled artisan would have been motivated to use β-1,3/1,6 glucan obtained from Aureobasidium pullulans because Japan Food Additive Association teaches that it is known to activate the immune system, which is essentially the purpose of Wagon's composition. The skilled artisan would have had a reasonable expectation of success because Japan Food Additive Association teaches that β-1,3/1,6 glucan is already in use as a health food.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keiichiro (JP 2001-048796, February 2, 2002, abstract, PTO-1449 submitted April 14,

2006) and Japan Food Additive Association (http://www.aureo.co.jp/english/glucan/glucan6.html, table from Explanatory Notes for Products in Existing Food Additives List, published 1999).

Keiichiro teaches an imunomodulator containing the killed cells of *Enterococcus faecalis* [abstract].

Japan Food Additive Association teaches as set forth above, that β-1,3/1,6 glucan obtained from Aureobasidium pullulan activates the immune system and can be used in a variety of foods [table].

Neither Keiichiro nor Japan Food Additive Association teaches a composition comprising both killed cells of *Enterococcus faecalis and* β-1,3/1,6 glucan.

The limitations "constipation-relieving drug", "immunopotentiator," and "skin moisturizer," as in claims 15-17, are considered intended use or inherent properties of the composition which are not given patentable weight; thus the claims are considered drawn to the composition only.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising both killed cells of *Enterococcus faecalis* and β-1,3/1,6 glucan and to use that composition in food or drink. The prior art teaches both elements and teaches that each is useful as an immunomodulator. One of ordinary skill in the art could have predicted that the combination of two immunomodulators would also be useful as an immunomodulator.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments and declaration of Koji Kubota filed December 12, 2007 have been fully considered but they are not persuasive.

Applicant presents the declaration of Koji Kubota to show that the glucan from Aureobasidium pullulans according to the invention has a higher viscosity that that of glucan of Wagon and provides a more uniform dispersion of bacterial cells than the glucan of Wagon. Applicant further argues that the prior art references used in the previous office action (and in this action as well) provide no suggestion or expectation of success to achieve a composition having the properties shown in the declaration of Koji Kubota.

The suggestion to prepare a composition comprising killed cells of *Enterococcus faecalis* and β-1,3/1,6 glucan from Aureobasidium pullulans is discussed in the above rejections. The superior viscosity and uniform dispersion of glucan from Aureobasidium

pullulans are expected properties because this glucan is already known as a thickener in food compositions. The skilled artisan would expect an effective thickener to have these properties. Thus, the claims are obvious as discussed in the above rejections.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623